EXHIBIT J

(Brief in Support of Plaintiffs' Motion to Stay)

Pfizer et al. v. Apotex et al.
Case No. 08 cv 7231

ADDENDUM

Pertinent Provisions of the Hatch Waxman Act

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The Hatch-Waxman Act

The Hatch-Waxman Act governs the approval of new and generic drugs. *See* 21 U.S.C. § 355; 35 U.S.C. §§ 156, 271(e) . It was devised with the aim of striking a "balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

Under Hatch-Waxman, a pioneer drug manufacturer that has had its drug approved by the FDA after submission of a New Drug Application ("NDA") is required to notify the FDA of all patents it owns "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). These patents then are listed in an FDA publication commonly referred to as the "Orange Book".[1]

Those seeking to market a generic copy of another company's pioneer drug may submit to the FDA an abbreviated new drug application ("ANDA"), which, rather than relying on extensive and costly independent safety and efficacy studies that an NDA must contain, may simply rely on the studies previously done by the pioneer. The generic manufacturer need only submit information showing the proposed generic copy's bioequivalence to the pioneer product. *See* 21 U.S.C. § 355(j)(2)(A). With the ANDA, the generic manufacturer must further include one of four certifications regarding each of

[1] The Orange Book is more formally known as *Approved Drug Products with Therapeutic Equivalence Evaluations, 29th Ed., U.S. Depart. Of Health and Human Services, Food and Drug Admin., Center for Drug Evaluation and Research, Office of Pharmaceutical Science, Office of Generic Drugs, 2009*.

the patents listed in the Orange Book for the pioneer drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV).

A paragraph IV certification is a statement that an Orange Book patent for the pioneer drug is invalid and/or not infringed by the proposed copy. In contrast, a paragraph III certification is a statement of the date on which a listed patent expires. If a paragraph III certification is submitted as Apotex has done with respect to Pfizer's '893 patent, the FDA will not approve the ANDA until the expiration of the patent.[2] Thus, Apotex's ANDA cannot be approved before March 24, 2010, the expiration date of the '893 patent. Absent FDA approval, Apotex's generic copy can not be sold legally in the United States.

Pertinent to the present motion, after receiving notice of any Paragraph IV certifications, the patent holder has only 45 days to sue the ANDA applicant for infringement. If the patent holder does not bring suit within this period, the FDA may approve the ANDA as soon as FDA has completed the review process. *See* 21 U.S.C. § 355(j)(5)(B)(iii). However, if the patent holder sues, the FDA may not approve the ANDA until entry of a final judgment that each relevant Orange Book patent is not infringed or is invalid, the patents expires, or thirty months have passed, whichever is earlier. *Id*.

To incentivize drug manufacturers to file ANDAs with Paragraph IV certifications that challenge Orange Book patents, the Hatch-Waxman scheme provides that the first generic manufacturer to file an ANDA with a Paragraph IV certification will be granted 180 days of market exclusivity. During this 180-day exclusivity period, the

[2] A paragraph I certification is that no patents have been listed. A paragraph II certification is that the relevant patents have already expired. Neither of these certifications are included in Apotex's ANDA in this matter.

FDA may not approve later filed ANDAs based on the pioneer's NDA. *See* 21 U.S.C. § 355(j)(5)(B)(iv).

Under the pre-2003 version of Hatch-Waxman, the 180-day exclusivity period could be "triggered" by either the first Paragraph IV ANDA filer's commercial marketing of its generic drug product, or a court decision of non-infringement or invalidity of the Orange Book patent. Importantly, before 2003 only the first Paragraph IV ANDA filer could begin the 180-day exclusivity period via the commercial-marketing trigger.

In December 2003 Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, 117 Stat. 2066 (2003). The MMA, Title XI, modified the exclusivity period triggering provisions with new "forfeiture" provisions. Under the current version of the statute, the 180-day exclusivity period is triggered only when the first ANDA filer takes its generic to market. However, the MMA sets forth a number of "forfeiture events" that result in the total elimination of the exclusivity period. *See* 21 U.S.C. § 355(j)(5)(D)(i). For example, the first ANDA filer that, for some reason, is not sued by the NDA holder, will lose its exclusivity period if it fails to go to market within 75 days after its ANDA is approved. 21 U.S.C. § 355(j)(5)(D)(i)(I)(aa)(AA). Likewise, the first or primary ANDA filer will lose its exclusivity period if it fails to take its generic to market within 75 days after a court judgment of invalidity or non-infringement. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA). Because Lipitor® was subject to ANDA challenge prior to the effective date of the MMA, the forfeiture provisions of the MMA do not apply to Apotex's ANDA. *See* MMA, Title XI, Sec. 1102. Forfeiture of 180-Day Exclusivity Period, ¶ (b) Effective date.

Under both the pre-2003 and current versions of Hatch-Waxman, a subsequent ANDA filer can trigger a prior ANDA filer's 180-day exclusivity period by obtaining a court decision that the NDA holder's Orange Book patents are invalid or not infringed.[3] *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1286 (Fed. Cir. 2008), *cert. denied*, No. 08-624, --- S. Ct. --- , 2009 WL 425097, 77 USLW 3308 (U.S. Feb. 23, 2009) ("[U]nder both the original and amended 180-day provisions, the ability of subsequent Paragraph IV ANDA filers to obtain FDA approval depends on the date of a final court decision holding the relevant Orange-Book-listed patents invalid or not infringed."). Congress also provided that an ANDA filer may invoke the relevant federal court declaratory judgment jurisdiction under 28 U.S.C. § 2201, but only "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5); *see also Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1335 (Fed. Cir. 2007) ("Title 35 U.S.C. § 271(e)(5) is a 2003 amendment to the patent statute that works in conjunction with the 2003 amendment to the ANDA statute" to provide declaratory judgment jurisdiction "to the extent consistent with the Constitution . . . .").

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[3] Under the pre-2003 Hatch-Waxman Act, a secondary ANDA filer that triggers the onset of the exclusivity period by a court judgment would need to wait a maximum of 180 days before going to market. However, under the current version of Hatch-Waxman, the waiting period could be extended to 254 days. This is because forfeiture of the 180-day exclusivity period would not take place until 75 days after the court judgment. Thus, after a court judgment, a primary ANDA filer could wait 74 days before going to market and then enjoy its exclusivity period for an additional 180 days, forcing the secondary filer wait 254 days total.